

REMARKS

Reconsideration is respectfully requested. Claims 1-2, 4-35, 40-55, and 58-59 are pending. Claims 1-2, 4-35, 40-55, and 58-59 are reiterated. On entry of this amendment, claim 59 has been added.

It appears that the Examiner has based the restriction requirement on the claims as filed instead of the claims as amended on February 9, 2002. For the Examiner's convenience, Applicants have reiterated the pending claims above.

Restriction Requirement

Applicants respectfully traverse the Restriction and submit that the asserted basis for the Restriction is insufficient. Applicants thus request the Restriction be reviewed and modified for the following reasons.

I. Restriction based on the alleged subgenera G1 and G2 is improper.

The Examiner has restricted Group 2 from Group 3 and Group 5 from Group 6 as allegedly patentably distinct based on alleged subgenera defined by the Examiner as "G1" and "G2." The Examiner defines G1 as a "subgenus ...limited to therapeutic agents, the identity of which can be discerned from the specification, and without referring to a patent or publication that has been 'incorporated by reference.'" The Examiner defines G2 as a "subgenus ...limited to therapeutic agents, the identity of which can only be determined referring to a patent or publication that has been 'incorporated by reference.'"

This difference utterly fails as a basis for restriction.

To provide a proper basis for restriction, the Examiner must establish 1) that the groups are independent or distinct, and 2) that there is must be a serious burden on the Examiner. See MPEP § 803. First, the Examiner has failed meet the burden of showing that groups G1 and G2 are independent inventions. MPEP § 802.01 provides that the term "independent" means that "there is no disclosed relationship between the two or more subjects disclosed, that is they are unconnected

in design, operation, or effect.” In the present case, applicants have incorporated some information by reference instead of simply repeating the information contained in the other document. MPEP §2163.07(b). The Examiner fails to point to any difference between therapeutic agents defined directly in the Specification, and therapeutic agents incorporated by reference that would lead to a conclusion that the subject matter incorporated directly into the Specification is an independent invention compared to the subject matter incorporated by reference.

Second, the Examiner has failed to meet the burden of showing that G1 and G2 are distinct inventions. MPEP § 802.01 provides that “two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof ..., but are capable of separate manufacture, use, or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER (though they may each be unpatentable because of the prior art)” (emphasis added; capital print as cited). The Examiner fails to point to any reasoning that would lead to a conclusion that the subject matter incorporated directly into the Specification is somehow a patentably distinct over the subject matter incorporated by reference. The Examiner thus fails to provide a basis to conclude that incorporating subject matter by reference, instead of repeating information contained in another document, creates a distinct invention.

Since the Examiner provides no reasoning or factual support to differentiate G1 and G2 as independent or distinct inventions, and appears instead to rely on an ad-hoc restriction methodology having no basis in law or PTO procedure, the Examiner has failed to establish that the so-called subgenera are independent and distinct inventions.

As such, Applicants respectfully request that the restriction between Groups 2 and 3 and between Groups 5 and 6 be withdrawn.

II. Restriction of Groups 1, 2, and 3 from Groups 4, 5, and 6 based on specific reactive groups is improper.

The Examiner has restricted Groups 1, 2, and 3 from Groups 4, 5, and 6 based on the presence or absence of a reactive group. The Examiner states that Groups 4, 5, and 6 are “drawn to

compounds in which a compound of [Group 1, 2, or 3 respectively] further includes a reactive group attached to the affinity group, and wherein the reactive group includes one of the functional groups that is recited in claim 21.”

Since the Examiner provided no reasoning in support of this restriction, it is unclear whether the Examiner is attempting to restrict the claims to compounds that include a reactive group from those that do not, or restrict claims directed to the specific reactive group species described in claim 21.

To the extent that the Examiner has attempted to restrict compounds of claim 1 that include a reactive group from compounds that do not include a reactive group, Applicants respectfully direct the Examiner to claim 1, which recites a reactive group R. Since all claims depend from claim 1, all claims contain a reactive group R.

To the extent that the Examiner is attempting to restrict the reactive group species claimed in claim 21 from other reactive groups, the Examiner has not met the requisite burden of showing that restricted groups are independent or distinct inventions. The Examiner has not provided any basis of support for the proposition that the specific reactive groups in claim 21 are independent from other reactive groups. Furthermore, the Examiner has not provided any reasoning to support the contention that the reactive groups of claim 21 are patentably distinct over other reactive groups. Absent such a basis, the Examiner has failed to establish that Groups 4, 5, and 6 are independent and distinct inventions.

As such, Applicants respectfully request that the restriction between Groups 1, 2, and 3 and Groups 4, 5, and 6 be withdrawn.

III. It would not be a serious burden to search Groups 1 and 4, where “E” is a diagnostic agent, together with Groups 2, 3, 5, and 6, where “E” is a therapeutic agent.

Applicants respectfully traverse the restrictions of Groups 1 and 4, where “E” is a diagnostic agent, together with Groups 2, 3, 5, and 6, where “E” is a therapeutic agent. There is no serious

burden on the Examiner to search the claims of the therapeutic agents and diagnostic agents. The compounds have the same formula $E-C_a-R-C_b-A$, and contain multiple additional limitations.

Applicants respectfully request that groups where "E" is a diagnostic agent and "E" is a therapeutic agent be rejoined.

IV. Group 7 is directed to previously cancelled claims.

The Examiner restricted claims 56 and 57 to Group 7. Claims 56 and 57 were canceled in a previous amendment.

V. Election

In the event that the instant Restriction Requirement is maintained despite the above discussion, Applicants provisionally elect Group 2.

Election of Species

With regard to the election of species requirement, Applicants hereby provisionally elect a species where:

- E is Argatroban
- C_a is $AEA_3-\beta Ala-Gly$
- R is $-O-Ph-C(O)-$
- C_b is absent (*i.e.* the molecule lacks a connector group C_b)
- A is $FIYEE-NH_2$.

Claim 59 currently reads on the elected species.

With regard to the election of species claim, Applicant's election is made without prejudice. Applicants acknowledge that upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, provided that all claims to each additional species are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

Conclusion

Applicant requests examination of the elected subject matter on the merits.

Applicant expressly reserves his/her right under 35 U.S.C. § 121 to file a divisional application directed to the nonelected subject matter during the pendency of this application, or an application claiming priority from this application.


In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented, and Applicants reserve the right to prosecute the subject matter of such claims in continuation and/or divisional applications.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **500862000700**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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